105TH CONGRESS 1ST SESSION

H. R. 2968

To require the Secretary of Health and Human Services to take no further action on proposed regulation relating to the use of chlorofluorocarbons in metered-dose inhalers.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 8, 1997

Mr. Smith of New Jersey (for himself and Mr. Stearns of Florida) introduced the following bill; which was referred to the Committee on Commerce

A BILL

- To require the Secretary of Health and Human Services to take no further action on proposed regulation relating to the use of chlorofluorocarbons in metered-dose inhalers.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. CHLOROFLUOROCARBONS IN METERED-DOSE
 - 4 INHALERS.
 - 5 In complying with Title VI of the Clean Air Act, 42
 - 6 U.S.C. 7671, and the Montreal Protocol on Substances
 - 7 that Deplete the Ozone Layer (Montreal Protocol), Sep-
 - 8 tember 16, 1987, S. Treaty Doc. No. 10, 100th Cong.,

- 1 1st session, regarding chlorofluorocarbons (CFCs), any
- 2 regulations under which the Secretary of Health and
- 3 Human Services may remove essential use designations
- 4 for the purpose of phasing out essential use allowances
- 5 for drug products shall require the Secretary of Health
- 6 and Human Services to certify to the Congress that alter-
- 7 natives to such inhalers are available that, for all popu-
- 8 lations of users of such inhalers, are comparable in terms
- 9 of safety and effectiveness, therapeutic indications, dosage
- 10 strength, cost, and retail availability.

11 SEC. 2. PROCESS FOR FURTHER RULEMAKING.

- 12 The Commissioner of the Food and Drug Administra-
- 13 tion shall withdraw the March 6, 1997 advance notice of
- 14 proposed rulemaking concerning CFCs in metered-dose in-
- 15 halers (MDIs) and shall issue another proposal only after
- 16 the 10th Meeting of the Parties to the Montreal Protocol
- 17 on Substances That Deplete the Ozone Layer. In carrying
- 18 out the goals of the Montreal Protocol to phase out essen-
- 19 tial use exemptions of CFC MDI products, the Food and
- 20 Drug Administration shall not prohibit the manufacture,
- 21 sale, or distribution of any CFC MDI product on the basis
- 22 that it is "adulterated" or "misbranded." Any subsequent
- 23 proposal shall be in the form of an advance notice of pro-
- 24 posed rulemaking and shall be initiated only after exten-
- 25 sive consultations with patients, physicians, other health

- 1 care providers, manufacturers of metered-dose inhalers,
- 2 and other stakeholders.

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